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| 10/539,234 | 07/15/2005 | Shirou Maeda | 2005_0752A | 7412 |
| 513 7590 02/13/2009 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021 | | | EXAMINER SCHLENTZ, NATHAN W | |
| | | | ART UNIT 1616 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,234

Applicant(s)

MAEDA ET AL.

Examiner

Nathan W. Schlientz

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 21-25, 27, 28, 30, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 is/are allowed.
- 6) ☒ Claim(s) 18, 21-24, 27, 28, 30, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 18, 27, 28 and 34 were amended and claim 36 was cancelled in an amendment filed 4 November 2008. As a result, claims 18, 21-25, 27, 28, 30, 34 and 35 are examined herein on the merits for patentability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

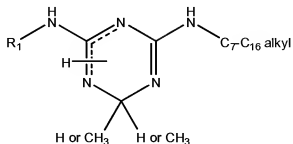
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 18, 21-24, 27, 28, 30, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moinet '122 (WO 01/55122, English language equivalent is US 2003/0109530 which is referred to herein).

Applicant's claims

Applicants claim a dihydrotriazine compound represented by the following formula:

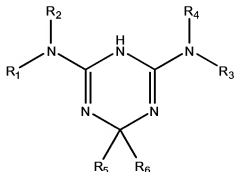


wherein R₁ is as defined in the instant claims. Claim 30 is drawn to an external bactericidal/disinfectant agent comprising the compound of claim 18. Claim 34 is drawn to a method for sterilizing/disinfecting comprising applying a compound as defined therein. Claim 35 is drawn to a method for preparing an external bactericidal/disinfectant agent comprising mixing the compound of claim 18 with a pharmaceutically acceptable additive.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Moinet '122 teaches compounds of the following formula:



wherein R₁, R₂, R₃, and R₄ are chosen independently from the groups including H and C₁₋₂₀ alkyl, C₃₋₈ cycloalkyl, C₃₋₈ heterocycloalkyl, C₆₋₁₄ aryl C₁₋₂₀ alkyl, C₆₋₁₄ aryl, and C₁₋₁₃

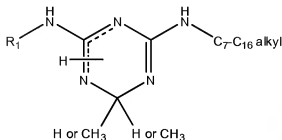
heteroaryl, wherein each substituent is optionally substituted; and R₅ and R₆ are chosen independently from the groups including H and C₁₋₂₀ alkyl ([0004]-[0019], [0036], [0039] and [0040]; and claims 1, 2 and 5). Moinet '122 teaches that the pharmaceutical compounds may be provided in forms intended for administration by the parenteral, oral, rectal, permucosal or percutaneous route ([0056]), wherein they are mixed with suitable excipients ([0057]-[0060]; and claim 9).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

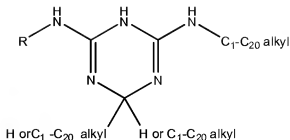
Moinet '122 do not specifically teach the exact same functional groups at the R₁, R₂, R₃, R₄, R₅, and R₆ substituents positions as instantly claimed. However, the functional groups at the substituents positions of Moinet '122 are substantially overlapping with the functional groups at the corresponding substituents positions of the instant claims, with the overlapping functional groups indicated below:

Compound of Claim 18



R_1 =phenyl, phenylalkyl, naphthyl, naphthylalkyl, heterocyclic, heterocycloalkyl, heterocycloaminoalkyl, cycloalkyl or cycloalkyl-alkyl

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R =cycloalkyl, heterocycloalkyl, arylalkyl, aryl or heteroaryl

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to synthesize compounds that are within the scope of the instant claims because Moinet '122 teaches a genus of compounds that overlap with the instantly claimed genus of compounds.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 18, 21-24, 27, 28, 30, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moinet '530 (US 2003/0109530) for the same reasons as indicated above.

3. Claims 18, 21-24, 27, 28, 30, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moinet '021 (US 7,034,021) for the same reasons as indicated above. Also, see claims 1, 2 and 5 wherein Moinet '021 teach the above drawn compound wherein R₁ and R₂ are independently chosen from only the groups H and C₁₋₂₀ alkyl, R₃ and R₄ are independently chosen from the groups including H and C₁₋₂₀ alkyl.

Allowable Subject Matter

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the compound according to claim 25, 4-octylamino-3,6-dihydro-6,6-dimethyl-2-(4'-methylbenzylamino)-1,3,5-triazine gluconate, is not taught by the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.